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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,371	07/31/2003	Ralph A. Heasley	287.1006	2138
23280	7590	12/15/2006	EXAMINER	
DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018				FUBARA, BLESSING M
ART UNIT		PAPER NUMBER		
		1618		

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/631,371	HEASLEY ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Blessing M. Fubara	1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 September 2006.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 25-37 is/are pending in the application.
  - 4a) Of the above claim(s) 25-34 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 35-37 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____.
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## **DETAILED ACTION**

Examiner acknowledges receipt of response to Election/Restriction requirement.

Amendment to the claims and remarks filed 9/25/06. Claims 1-24 are canceled. Claims 25-37 are pending.

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II in the reply filed on 9/25/06 is acknowledged.

Applicant further elected gastrointestinal side effects. Applicant did not identify the claims that read on the elected species. However, upon consideration of the elected condition for prosecution on the merits, claims 35 to 37 are identified as reading on the elected species. Therefore, claims 25-36 are withdrawn from consideration and claims 35-37 are examined.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Gastrointestinal side effects are conditions that are caused by either drugs or food. In the claims 35-37, there is no indication of what the adverse side effects are or what the adverse side effects are caused by. However, to advance prosecution and to enable search for the claims,

terms such nausea or vomit(ing) or diarrhea or cramp(ing) or flatulence, which are side effects of the GI either due to drug or food, are considered in the search. Clarification is requested.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 35-37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lerner et al. (US 6,197,331).

The invention in claims 35-37 orally administers effective amount of delayed release pharmaceutical (claim 37), extended release pharmaceutical (claim 35) and effective amount of pharmaceutical to effect reduction of gastrointestinal side effects. Delayed release and extended release are forms of controlled/sustained release.

Lerner discloses oral controlled or sustained release formulation that comprises active agent and carrier such as EUDRAGIT polymers (column 7, lines 43-49; column 8, lines 2-12; column 10, lines 16-67; column 11, lines 1-15), hydroxypropylmethylcellulose, gelatin, starch and methacrylate (column 11, lines 16-53). The gelatin, starch and cellulose are some of the excipients named in applicant's specification as delaying or contributing to the controlled release of the active (see paragraph [0022] of the published application). Therefore, hydroxypropylmethylcellulose, EUDRAGIT, starch and gelatin meet the requirements for an agent that controls the release. One class of active agent is the hemostatic agents and one of the

drugs named in this group of drugs if tranexamic acid which is the same as the recited drug. No specific oral drug form is claimed and the oral delivery dosage form of the prior art meets the drug form that is administered in the instant claims. Vomiting, nausea, gerd and reflux disease are some of the conditions treated by Lerner (column 17, lines 1-7). Thus Lerner meets the limitations of the claims.

In the alternate, the fact that the drug formulation of the prior art comprises the same excipients named in applicant's specification as contributing to controlled/sustained release of the tranexamic acid, therefore the presence of these excipients in the formulation of Lerner lends to the inherent ability of the formulation of the prior art to be delivered/released at any where in the GI tract. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the oral formulation of Lerner to treat Vomiting, nausea, gerd and/or reflux disease and expect the tranexamic acid to be released anywhere along the GI tract since the excipients of Lerner are known to control release of drugs.

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Blessing Fubara   
Patent Examiner  
Tech. Center 1600